IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Douglas Van Drie, M.D.)

The plaintiffs filed their Notice of Adoption of Prior Daubert Motion of Douglas Van Drie, M.D. for Waves 4 and 5 Cases ("Notice") [ECF No. 4551] in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, on September 27, 2017. The plaintiffs attached as exhibits to their Notice a motion [ECF No. 4551-1], memorandum in support [ECF No. 4551-2], and reply brief [ECF 4551-3], which plaintiffs seek to adopt and incorporate as their briefing for Waves 4 and 5. The defendant also adopted and incorporated by Notice of Adoption of C.R. Bard, Inc.'s Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude Certain General Opinions and Testimony of Douglas Van Drie, M.D., for Wave 4 and Wave 5 Cases, a brief in response to the plaintiffs' Motion. [ECF No. 4647]. The court construes the plaintiffs' Notice as a motion. As such, the Notice is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' Motion is **GRANTED in part** and **RESERVED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses,

and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

Before plunging into the heart of the motion, and to clarify the record, I am compelled to comment on the manner in which the parties filed the instant *Daubert* motion and response in opposition. Similar to other *Dauberts* filed in the main MDL, the plaintiffs filed the instant motion as a "Notice," adopting and incorporating the entirety of a motion and its corresponding papers filed in a previous case before the court. Defendant C. R. Bard, Inc. ("Bard"), likewise, filed its opposing briefs in conjunction with a similar "Notice." The parties then attached the substance of their briefs, i.e., the supporting or opposing memorandum of law, as an exhibit to their respective Notice. So, for example, the plaintiffs attach the memorandum in support of their *Daubert* motion as "Exhibit 1" to their Notice. The plaintiffs also integrate into Exhibit 1 vital supporting papers, such as the expert report within Exhibit 1 rather confusingly as "Exhibit 1," forming one large document. With this in mind, the court turns its attention to the present dispute.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles

and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the

particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Van Drie is an urogynecologist and Director of the Female Pelvic Medicine and Urogynecology Institute of Michigan in Grand Rapids, Michigan. He serves as a clinical professor of OB/GYN at the Michigan State University College of Medicine. He has thirty-five years of experience treating women with pelvic floor disorders, and has performed more than 3000 pelvic floor surgeries.

A. Shrinkage and Degradation

First, the plaintiffs seek to exclude Dr. Van Drie's opinions that polypropylene mesh does not shrink or degrade inside the body. The plaintiffs assert that Dr. Van Drie's opinions are unreliable because they are based solely on his personal clinical experience and because he failed to sufficiently consider scientific literature that is contrary to his view. Bard responds that Dr. Van Drie's opinions that polypropylene mesh does not shrink or degrade inside the body are based on his clinical experience, during which he did not observe evidence of shrinkage or degradation, and upon his review of the relevant medical and scientific literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented

with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g.*, *Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Van Drie has based his opinions on his extensive clinical experience and a review of the medical and scientific literature; in the abstract, these are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Van Drie did not observe evidence of mesh shrinkage or degradation because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical

community or medical literature can be difficult to assess. Although the expert report indicates Dr. Van Drie reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Van Drie's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

B. Material Safety Data Sheet ("MSDS")

Second, plaintiffs seek to exclude Dr. Van Drie's opinions regarding the MSDS for Marlex polypropylene resin issued by Chevron Phillips. Specifically, Dr. Van Drie opines that

> As a physician, I use numerous medical products a week and have never reviewed a MSDS on any of them. As I understand it, the MSDS is meant to apply to the safety of the manufacturing process and not to the finished product's user. Any indication that mesh should not be implanted in the human body refutes decades of surgical use and evidence based literature. It's my understanding that such language was added for legal reasons to protect the company form any products liability lawsuits.

Van Drie Report 20.

Regarding the last sentence of Dr. Van Drie's opinion quoted above, this constitutes improper "state of mind" testimony. Experts may not testify about what other parties did or did not know, or their supposed intent behind their actions.

Therefore, Dr. Van Drie's opinion that the MSDS "was added for legal reason" is **EXCLUDED**. The plaintiffs' motion is **GRANTED** on this point.

Regarding the remainder of Dr. Van Drie's opinion, his and other doctors' experience with the MSDS for raw polypropylene pellets is not relevant or helpful to the jury. The pertinent issue is not whether doctors rely on or heed MSDS warnings for the raw materials Bard uses to manufacture its medical devices. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 577 (S.D. W. Va. 2014) (excluding a doctor's opinions on the MSDS because "[a] narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury"). Nevertheless, I acknowledge the need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Van Drie's remaining MSDS opinions for trial.

IV. Conclusion

To summarize, I **GRANT in part** and **RESERVE in part** the plaintiffs' Notice of Adoption of Prior Daubert Motion of Douglas Van Drie, M.D. for Waves 4 and 5 Cases [ECF No. 4551], which the court has construed as a motion, consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 5, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.